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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/090,358	TUMEY, DAVID	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-10 and 21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *27-30* is/are allowed.

6)☒ Claim(s) *1,6,10,21 and 22* is/are rejected.

7)☒ Claim(s) *5,7-9,23-26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see Remarks, filed November 19, 2009, with respect to the rejections of claims 5, 7-9 and 23-28 under 35 U.S.C. 103 have been fully considered and are persuasive. The rejections of claims 5, 7-9 and 23-28 under 35 U.S.C. 103 have been withdrawn.

2. Applicant's arguments filed November 19, 2009 with respect to the rejection of claims 1, 6, 10, 21 and 22 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Johnson repeatedly mentions the benefit of more rapid wound healing via impregnation of a tissue growth factor on the foam pad that contacts the wound. It is the examiner's position that one of ordinary skill in the art of employing tissue growth factor to repair wounds is aware that the presence and activity of growth factor can be discerned by different types of chromatography. Further, the progress of the regrowth of tissue could be more accurately monitored (compared to visual monitoring) by gas chromatography which, in addition to indicating the level of growth factor present, can also indicate the presence of undesired organisms or cells. Overton discloses a portable gas chromatograph which can be used with any sample capable of being analyzed via gas chromatography, including wound exudate. As

the device of Johnson is largely portable, and the GC of Overton is also portable, and in light of the desirability of accurate monitoring of a wound environment to correctly gauge progress of healing, the examiner maintains that it would be obvious to one of ordinary skill in the art to use the GC of Overton in the device of Johnson.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 6, 10, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (WO 00/59424 A1) in view of Overton et al (U.S. Patent No. 5,611,846).

With respect to **claim 1:** Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source fluidically communicating with said screen means 11 via material hose 14.

Johnson does not teach a gas chromatograph operable to sense compositional characteristics of unfiltered wound fluid from the wound bed interposed between said screen means 11 and said vacuum source. Johnson also does not disclose or suggest a gas chromatograph that further comprises a photodiode operable in optical proximity to fluids being drawn from the wound bed toward said vacuum source, wherein the gas chromatograph detects a light frequency as the fluids pass the photodiode. Overton discloses a gas chromatograph (GC) that is a chromatograph disclosed by applicant for use with the claimed device and is thus

necessarily operable to sense compositional characteristics of unfiltered wound fluid from the wound bed. The GC necessarily further comprises a photo diode inasmuch as Overton discloses that a photoionization detector (PID) 212 is electrically connected to the column to detect a change in conductivity. A photo diode is given its common meaning in the interpretation of claim 1, i.e. a photodetector capable of turning light into current or voltage. ('846, Col. 12, lines 20-28) The photodiode in the form of PID 212 is operable in optical proximity to fluids being passed through column 210. The GC with PID 212 therein detects a light frequency, specifically UV light from source 222 associated with a change in conductivity as a result of passing the light through the gas stream. Overton discloses a computer processing unit in the form of a data processing module that necessarily stores light frequencies or changes therein because Overton discloses comparisons to different columns from the same device which employs a photodetector to determine the identity of analytes. Thus Overton discloses a computer processing unit comprising a database that stores light frequencies associated with microorganisms, i.e. the analytes. The device of Overton also comprises a software program operable to compare the light frequency detected by the GC with light frequencies stored in the database to identify the analytes. ('846, Col. 3, lines 41-53) Overton discloses that this GC is portable and operates at high speed with minimal consumption of utilities. ('846, Abstract) Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Johnson so as to comprise a gas chromatograph, computer processing unit and software program as disclosed by Overton to allow identification of analytes in unfiltered wound fluid to determine the physiological status of the wound bed environment for diagnostic purposes. The GC of the device of Johnson as modified by Overton would thus comprise a photo diode operable in optical proximity to fluids being drawn from the wound bed through the GC column toward the

vacuum source, wherein the GC detects a light frequency (specifically, UV light) as the fluids pass the photodiode.

With respect to **claim 6:** Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source fluidically communicating with said screen means 11 via material hose 14 (flexible conduit for communicating between screen means and vacuum source). Johnson teaches a collection canister interposed between said screen means and said vacuum source. (Page 4, lines 18-21)

Johnson does not teach a sensor array operable to sense compositional characteristics of unfiltered wound fluid from the wound bed interposed between said screen means 11 and said vacuum source. Overton discloses a sensor array in the form of a GC having a combined photoionization detector/flame ionization detector wherein the detectors are in series, defining a sensor array. The chromatograph disclosed by Overton is disclosed by applicant as a GC for use with the claimed device and thus the array is necessarily operable to sense compositional characteristics of unfiltered wound fluid from the wound bed. Overton discloses that this GC is portable and operates at high speed with minimal consumption of utilities. ('846, Abstract) Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Johnson so as to comprise a gas chromatograph, computer processing unit and software program as disclosed by Overton to allow identification of analytes in unfiltered wound fluid to determine the physiological status of the wound bed environment for diagnostic purposes. The GC of the

device of Johnson as modified by Overton would thus comprise a photo diode operable in optical proximity to fluids being drawn from the wound bed through the GC column toward the vacuum source, wherein the GC detects a light frequency (specifically, UV light) as the fluids pass the photodiode. Thus, the compositional characteristics detected by the GC of Overton when used with the device of Johnson are necessarily indicative of infection as the presence of any bacterium would be detected by the GC via said data processing module. If the fluid passing through the column of the GC is wound exudate as would be the case, the compositional characteristics necessarily include a presence of a bacterium. The sensor array would also necessarily comprise regions of conducting nonorganic material (i.e the compressed gas in the gas stream) and regions of conducting organic material, i.e. wound exudate, compositionally different than the nonconducting organic material.

With respect to **claim 10:** The negative pressure therapy device of Johnson further comprises a flexible conduit in the form of material hose 14 for communicating between said screen means 11 and said vacuum source.

With respect to **claim 21:** The microorganisms disclosed by Johnsons in the wound exudate necessarily include an antigen. Examiner's position is based upon Johnson's disclosure of modification of the screen means 11 for introduction of a growth factor which would not be necessary or perform its intended function if an antigen were not present. ('240, Col. 3, lines 59-64)

With respect to **claim 22:** The negative pressure therapy device of Johnson as modified by Overton further comprises a display in the form of a chromatogram operable to transmit visual

notification if the software program identifies a match between the light frequency detected by the gas chromatograph and at least one of the light frequencies stored in the database, inasmuch as the chromatogram identifies the substance by a code, e.g. C17 (see Figs. 9 and 10), which can only be obtained subsequent to matching the detector results with previously stored chromatograms.

Allowable Subject Matter

5. Claims 27-30 are allowed.

6. Claims 5, 7-9 and 23-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Indicating Allowable Subject Matter

7. The following is a statement of reasons for the indication of allowable subject matter:

a. with respect to claim 5, though the examiner maintains the rejection of claim 1 stating that it would be obvious to use the GC of Overton with the Johnson device, since Johnson neither discloses nor suggests a GC, it would not be obvious to one of ordinary skill in the art to first modify the device of Johnson so as to include a GC and then further modify the resulting device such that the GC is specifically positioned between the canister and the foam pad disclosed by Johnson;

b. with respect to claims 7 and 24, since Johnson neither discloses nor suggests a sensor array, it would not be obvious to one of ordinary skill in the art to first modify the device of Johnson so as to include a sensor array and then further modify the resulting device such that the sensor array is specifically embedded in the foam pad;

c. with respect to claims 8 and 25, since Johnson neither discloses nor suggests a sensor array, it would not be obvious to one of ordinary skill in the art to first modify the device of Johnson so as to include a sensor array and then further modify the resulting device such that the sensor array is specifically disposed on the drape such that the sensory array is in contact with the foam pad;

d. with respect to claims 9 and 26, since Johnson neither discloses nor suggests a sensor array, it would not be obvious to one of ordinary skill in the art to first modify the device of Johnson so as to include a sensor array and then further modify the resulting device such that the sensor array is specifically disposed within the canister;

e. with respect to claim 23, since Johnson neither discloses nor suggests a sensor array, it would not be obvious to one of ordinary skill in the art to first modify the device of Johnson so as to include a sensor array and then further modify the resulting device such that the sensor array is specifically disposed between the wound bed and the filtration mechanism.

Reasons for Allowance

8. The following is an examiner's statement of reasons for allowance: With respect to claim 27, since Johnson neither discloses nor suggests a GC, it would not be obvious to one of ordinary skill in the art to first modify the device of Johnson so as to include a GC and then further modify the resulting device such that the GC is specifically positioned between the foam pad and the vacuum source, and then also modify the resulting device such that the GC is specifically disposed between the wound bed and the filtration mechanism. Claims 28-30 depend from claim 27 and are thus also allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761